REMARKS

Introductory Comments:

Claims 1, 3, 4 and 6-8 were examined in the Office Action under reply and stand variously rejected under (1) 35 U.S.C. §112, first paragraph (claims 1, 3, 4, and 6-8); (2) 35 U.S.C. §112, second paragraph (claim 3); and (3) 35 U.S.C. §102(e) (claims 1, 4, 7 and 8). These rejections are respectfully traversed as discussed more fully below.

Overview of the Above Amendments:

Claims 1 and 3 have been amended to recite the subject invention with greater particularity. Specifically, claim 1 now defines the *C. parvum* polypeptide claimed relative to SEQ ID NO:4. Moreover, the polypeptide "elicits an equivalent or enhanced immunological response" as compared to the polypeptide comprising the sequence of amino acids depicted at amino acid positions 1-193 of Figure 2B (SEQ ID NO:4). Claim 3 has been amended to recite "90% sequence identity" to the reference sequence and to delete the recitation of fragments.

Non-elected claims 2, 5 and 9-31 have been cancelled and new claims 32-35 added. The new claims are analogous to claims 1, 4, 7 and 8 but recite that the polypeptide comprises the sequence of amino acids depicted at amino acid positions 1-193 of Figure 2B (SEQ ID NO:4). Support for this amendment can be found throughout the specification at, e.g., page 12, line 10 and page 14, lines 9-11.

The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications containing the unamended claims. Moreover, the above amendments do not present new issues that would require an additional search. Accordingly, entry of the foregoing amendments and new claims is respectfully requested.

Rejection Under 35 U.S.C. §112, First Paragraph:

Claims 1, 3, 4 and 6-8 remain rejected under the written description clause of 35 U.S.C. §112, first paragraph. The Office directs applicant to examples in the Revised Interim

Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("the Revised Interim Guidelines") and asserts:

> Any peptide of 5 or greater amino acids under the right conditions will elicit an immune response. Consequently, Applicants claimed function of 'immunogenicity' in no way identifies members of a genus, since every single one of the polypeptides is capable of 'immunogenicity.'

Office Action, page 3. However, applicant respectfully submits that the claims indeed comply with the written description requirement of 35 U.S.C. §112, first paragraph.

In particular, the Examiner's attention is directed to Example 14 of the Revised Interim Guidelines. This example specifically examines a claim reciting variants of a specified sequence that are "at least 95% identical" to the reference sequence and that "catalyze the reaction" of A to B. The example acknowledges that the procedure for making variants i.e., proteins with substitutions, deletions, insertions and additions, is routine in the art. Additionally, the specification provides an assay for detecting the catalytic activity of the proteins. Moreover, there is an actual reduction to practice of the single disclosed reference sequence. The Revised Interim Guidelines state:

> One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus.
> **Conclusion**: The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.

Similarly, claims 1, 3, 4 and 6-8 of the present application comply with the requirements of 35 U.S.C. §112, first paragraph.

Claims 1 and 3 of the present application (and claims 4 and 6-8 which depend therefrom) recite that the variant sequences have "90%" sequence identity to the reference sequence. Moreover, the variant sequence or fragment "elicits an equivalent or enhanced immunological response" as compared to the reference sequence. As in the example above, applicant has actually cloned the nucleic acid sequence of SEQ ID NO:3 and obtained the protein of SEQ ID NO:4. Applicant has explained in the specification that the contemplated variants include deletions, additions and substitutions to the sequence. See, e.g., page 8, lines 14-16; and page 13, line 30 to page 14, line 4. Applicant has detailed procedures for finding immunogenic portions of the proteins. See, e.g., pages 9-10, bridging paragraph. Moreover, tests for

determining immunogenicity are well known in the art. Thus, as in the example above, applicants have specified a structure along with a common attribute possessed by the members of the genus. Accordingly, the disclosure meets the requirements of 35 U.S.C. §112, first paragraph.

The Office also states "SEQ ID NO:4 does not appear to be a full length protein, given that the classical start codon, methionine, is absent." However, applicants point out that the ATG codon encoding methionine was provided by the vector in which the sequence was subcloned. The AG2 protein was expressed as a fusion. See, example 2 of the application. Applicants are providing a map and explanation of vector pET-11a, the vector used to clone AG1. This vector is analogous to the vector used to clone AG2. As shown, the *NdeI/NheI* junction provides the ATG codon. Thus, the Office's analysis is in error.

Based on the foregoing, withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

Rejection Under 35 U.S.C. §112, First Paragraph:

Claim 3 was rejected under 35 U.S.C. §112, second paragraph based on the term "about." This term no longer appears in claim 3. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Rejection Under 35 U.S.C. §102(e):

Claims 1, 4 and 7-8 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,323,020, to Perryman et al. The Office maintains the rejection, arguing that these claims lack reference to a sequence identifier and that "the nucleic acid disclosed by Perryman *et al.* encodes a *C. parvum* polypeptide with a molecular weight of 23 kDa." Office Action, pages 7-8, bridging paragraph. Applicants respectfully traverse.

In particular, claim 1 (and hence claims 4, 7 and 8 which depend from claim 1) recites the sequence of SEQ ID NO:4. As explained in the previous response, a comparison between applicant's SEQ ID NO:4 (193 amino acids) and Perryman's SEQ ID NO:2 (111 amino acids) showed no significant homology. Thus, Perryman does not anticipate the claims and withdrawal of this basis for rejection is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested. If the Examiner notes any further matters which he believes may be resolved by a telephone interview, he is encouraged to contact the undersigned by telephone at 650-493-3400.

Respectfully submitted,

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